

REMARKS

Responsive to the Office Action mailed June 27, 2007, Applicants hereby file the following amendment and remarks.

The disclosure has been objected to because of the use of trademark names to identify products generally known to those of skill in the art. Applicants submit amended paragraphs herein and thank the Examiner for pointing these issues out. The actual trademark registration for ELISPOT is dead but the product is attributed to its source herein. With respect to ZIPLOC, Applicants believe that this product is "well-known and satisfactorily defined in the literature." (MPEP 608.01(v)). Additionally, a new abstract is herewith provided.

The claims have been objected to because of their spacing and this has been corrected herein.

Claims 1, 2, 23, 25 and 26 are currently pending. Claims 5-20 are canceled herewith. Claims 3-4, 21-22 and 27-63 are withdrawn from consideration. No claims have been allowed.

Claims 8, 9, 12, 13, 15 and 18 are rejected under the second paragraph of 35 USC 112 for indefiniteness. As these claims have been canceled herewith, this rejection is obviated.

Claims 1, 2, 5-10, 12-15, 25 and 26 are rejected under USC 103(a) as unpatentable over Minnich in view of Lehmann et al. To the extent this rejection applies to currently pending claims, it is respectfully traversed.

Minnich concerns methods of rapidly determining microbe contamination in water. Lehmann relates to devices and methods for detecting cellular products, such as cytokines from individual cells in a mixture of heterogeneous cells, particularly T cells. As such, the combination of references is an inapposite one to suggest the present invention, which is directed to enumerating microbial colonies in a sample. Minnich does not teach counting colonies on the plate, to which claim 1 is drawn, and is directed in particular to detection and quantification of coliform bacteria such as *E. coli* in drinking water. The second full paragraph in the "Experimental Section" of this patent recites:

A specified water sample is filtered through a designed cassette containing a hydrophobic membrane filter with a designated number of separate compartments. Microorganisms present in the water sample are then evenly distributed over a compartmentalized filter. Since the microorganisms to be quantified are in low numbers in potable water, an enrichment step is employed to raise the number of microorganisms to detectable levels. This is accomplished by overlaying each compartment well of the membrane filter

cassette with a small volume of non-selective media (e.g. phenol red lactose broth supplemented with 4-methyl-umbelliferone D-glucuronide). The filter cassette with added medium is then incubated at 35.degree. C. for a designated period of time and then scored for those compartment wells showing an acid reaction based on the pH indicator in the medium. Lactose is the sole carbon source in the medium, therefore acid production will indicate a presumptive positive test for coliform bacteria.

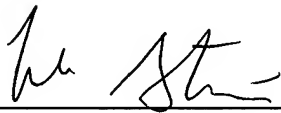
It would be unlikely for a person of ordinary skill in the art to combine the teaching of this patent with the teaching of Lehmann, which sets for a method of detecting secretion of particular cytokines by T cells, wherein membranes in a multiwell plate are bound with ligands specific to cytokines in order to arrive at a method to count colonies in a microbial sample. Although the two references contain a good deal of information that might be pulled out of context, they do not, when combined, teach or suggest all the elements of the claims under examination. As KSR notes, "A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known..." (*KSR International Co. v. Teleflex, Inc.*, 530 US 14 2007).

Claims 1, 2, 5-10, 12-15, 25 and 26 are further rejected under USC 103(a) as unpatentable over Young et al. in view of Lehmann et al. To the extent this rejection applies to currently pending claims, it is respectfully traversed. Because Lehmann is directed to detecting the presence of factors secreted by T cells and because Young is similar in scope and content to Minnich, discussed above, it is suggested that not only do the references not teach the claimed invention, but the skilled artisan would be unlikely to combine such disparate sources. Again, KSR reiterates that the analysis "must be made explicit" (*KSR* at 14; citing *In Re Kahn*, "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning..." 441 F.3d, 977, 988 CAFC 2006). Therefore, Applicants would argue that there is no reason for the skilled artisan to combine teachings from a patent concerning contamination of a potable water with a patent concerning secretory cytokines and arrive at the claims of the instant invention.

It is submitted that the instant claims are free of the prior art and in condition for allowance. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response.

No fee is believed due. However, in the event that any fees are deemed necessary, please charge deposit account 13-2755. If any time extensions are needed for the timely filing of the present amendment, applicants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By 

Heidi M. Struse  
Reg. No. 50,288  
Attorney for Applicants

Merck & Co., Inc.  
P.O. Box 2000  
Rahway, NJ 07065-0907  
(732) 594-0238

Date: September 27, 2007